(3) *Packaging.* The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) *Receipt of an organ.* Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in accordance with paragraph (b)(2) of this section.

(e) *Blood vessels considered part of an organ.* A blood vessel that is considered part of an organ under this part shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.

(f) *Wastage.* Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56659, Oct. 20, 1999; 72 FR 10925, Mar. 12, 2007]

§ 121.8 Allocation of organs.

(a) *Policy development.* The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section.

(b) *Allocation performance goals.* Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

(1) Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists;

(2) Setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent (taking into account, in accordance with paragraph (a) of this section, and in particular in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency;

(3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)–(5) of this section, and in order of decreasing medical urgency; and

(4) Applying appropriate performance indicators to assess transplant program performance under paragraphs (c)(2)(i) and (c)(2)(ii) of this section and reducing the inter-transplant program variance to as small as can reasonably be achieved in any performance indicator under paragraph (c)(2)(iii) of this section as the Board determines appropriate, and under paragraph (c)(2)(iv) of this section. If the performance indicator ''waiting time in status'' is used for allocation purposes, the OPTN shall seek to reduce the inter-transplant program variance in this indicator, as well as in other selected performance indicators, to as small as can reasonably be achieved, unless to do so would result in transplanting less medically urgent patients or less medically urgent patients within a category of patients.

(c) *Allocation performance indicators.* (1) Each organ-specific allocation policy shall include performance indicators. These indicators must measure how well each policy is:

(i) Achieving the performance goals set out in paragraph (b) of this section; and

(ii) Giving patients, their families, their physicians, and others timely and accurate information to assess the performance of transplant programs.

(2) Performance indicators shall include:

(i) Baseline data on how closely the results of current allocation policies approach the performance goals established under paragraph (b) of this section;

(ii) With respect to any proposed change, the amount of projected improvement in approaching the performance goals established under paragraph (b) of this section;

(iii) Such other indicators as the Board may propose and the Secretary approves; and

(iv) Such other indicators as the Secretary may require.

(3) For each organ-specific allocation policy, the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor. Such data shall be required on performance by organ and status category, including program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the Nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include the following measures of inter-transplant program variation: risk-adjusted total life-years pre-and post-transplant, risk-adjusted patient and graft survival rates following transplantation, risk-adjusted waiting time and risk-adjusted transplantation rates, as well as data regarding patients whose status or medical urgency was misclassified and patients who were inappropriately kept off a waiting list or retained on a waiting list. Such data shall cover such intervals of time, and be presented using confidence intervals or other measures of variance, as may be required to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(d) *Transition patient protections*—(1) *General.* When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(2) *Special rule for initial revision of liver allocation policies.* When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (e)(1) of this section, it shall include transition procedures that, to the extent feasible, treat each individual on the waiting list and awaiting transplantation on October 20, 1999 no less favorably than he or she would have been treated had the revised liver allocation policies not

become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after accommodating a substantial preponderance of those disadvantaged by the change in the policies.

(e) *Deadlines for initial reviews.* (1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (e)(2) of this section, no later than November 16, 2000 shall transmit initial revised policies to meet the requirements of paragraphs (a) and (b) of this section, together with supporting documentation to the Secretary for review in accordance with §121.4.

(2) No later than March 16, 2000 the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements of paragraphs (a) and (b) of this section to the Secretary for review in accordance with §121.4. The OPTN may transmit these materials without seeking further public comment under §121.4(b).

(f) *Secretarial review of policies, performance indicators, and transition patient protections.* The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraphs (c) and (d) of this section.

(g) *Variances.* The OPTN may develop, in accordance with §121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of §121.4.

(h) *Directed donation.* Nothing in this section shall prohibit the allocation of an organ to a recipient named by those authorized to make the donation.

[64 FR 56659, Oct. 20, 1999, as amended at 64 FR 71626, Dec. 21, 1999]

§121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under §121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under §121.4;

(iv) Has available operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel;

(v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;

(vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology, and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and

(vii) Makes available psychiatric and social support services for transplant candidates, transplant recipients, and their families; or

(3) Be a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.